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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,526	06/24/2003	William R. Noyes	3222.01US02	1769
62274	7590	10/11/2006	EXAMINER	
DARDI & ASSOCIATES, PLLC 220 S. 6TH ST. SUITE 2000, U.S. BANK PLAZA MINNEAPOLIS, MN 55402			SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/602,526	Applicant(s) NOYES, WILLIAM R.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 39-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
HUMERA N. SHEIKH
PRIMARY EXAMINER
TC-1600

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/22/03; 7/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response to Election/Restriction requirement and Applicant's Arguments/Remarks, both filed 07/20/06 and the Information Disclosure Statements (IDS) filed 09/22/03 & 07/15/04 and the Power of Attorney Notice filed 07/19/06 is acknowledged.

Applicant's election of Group IV (Claims 17-38) and the Election of Species (polyethylene glycol) in the reply filed on 07/20/06 is acknowledged. Applicant's request of rejoinder of claims in Groups I, III and IV upon allowance of linking claims 33 and 35 is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-16 and 39-61 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-61 are pending in this action. Claims 1-16 and 39-61 have been withdrawn. Claims 17-38 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tihon *et al.* (U.S. Pat. No. 5,499,994) in view of Gokcen (U.S. Pat. No. 6,913,744).

The instant invention is drawn to a method comprising introducing a filler to between a first tissue location and a second tissue location to increase a distance between the first tissue location and the second tissue location, and administering a dose of radioactivity to at least the first tissue location or second tissue location.

Tihon *et al.* ('994) teach methods for the treatment of hypertrophy of the prostate gland and methods for dilating an unobstructed portion of the urethra. Tihon *et al.* also teach dilation devices for the urethra for treating benign prostate hyperplasia (see reference column 1, lines 6-13) and Abstract. The methods for treatment are less invasive and less painful than previous methods (col. 1, line 66 – col. 2, line 2).

Tihon *et al.* employs hydrophilic means, which can be any biologically compatible materials such as hydrogels which are capable of expanding slowly when water is absorbed therein (col. 3, lines 52-55).

The hydrophilic particles must be capable of gradually (as opposed to rapidly) expanding. This provides a maximum of comfort to the patient (col. 7, lines 52-58).

Suitable hydrophilic materials taught include polyethylene glycol and hyaluronic acid (col. 7, lines 59-64). The concentration of the hydrophilic material will also affect the rate of expansion. A high concentration of such material will speed the rate of expansion. Also, a high osmolarity, or charge content, will speed the rate of swelling (col. 8, lines 5-11). The hydrophilic material should have a gradual, slow dilation that occurs over a period of at least 30 minutes and preferably over a much longer period (col. 8, lines 33-46). The expandable device can be an expanding bag stent (col. 8, lines 47-65).

Tihon *et al.* do not teach administering radioactivity to tissue and do not teach a therapeutic agent (*i.e.*, antibiotic).

Gokcen ('744) teaches a method and composition for treating prostate cancer whereby suitable methods of treatment disclosed include administering radiation (see column 1, lines 50-51).

The composition can include an active agent, such as an antibiotic (col. 2, lines 37-40). Antibiotics usually relieve symptoms of acute prostatic infections promptly (col. 7, lines 66-67).

The method of treatment can be carried out by transrectal routes of prostatic injections (col. 12, lines 11-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the radiation methods and active agents, such as antibiotics, as taught by Gokcen within the treatment methods of Tihon *et al.* One of ordinary skill in that art would

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be motivated to do so with a reasonable expectation of success because Gokcen teaches that suitable and effective methods for treatment of prostate cancer include administering radiation, dependent on factors such as age of patient and severity of condition and also teach that active agents, such as antibiotics are added to the composition to promptly relieve symptoms of acute prostatic infections. The expected result would be an improved, safe and effective method for treating prostatic conditions in a patient.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

September 29, 2006

Humera N. Sheikh
TC-1600

hns